

PATENT  
USSN 10/054,611  
Docket 002970US; 018/182c

### REMARKS

This paper is supplemental to the Amendments filed in this application on May 27, 2004, and July 26, 2004. The Amendment filed May 27, 2004 was fully responsive to the most recent Office Action on the merits, mailed on January 5, 2004.

Certain claims have been amended, and product claims 27-34 have been cancelled. Claims 1-19, 21, and 35-46 are pending and under examination. Claims 23-26 are pending but withdrawn from examination.

Further consideration and allowance of the application is respectfully requested in view of the claim amendments and remarks presented previously and herein.

#### Interview Summary:

The undersigned wishes to express his gratitude to Examiner Malgorzata Walicka and Examiner Rebecca Prouty for the helpful and constructive interview held at the Patent Office on September 2, 2004. Possible amendments to the claims were discussed. This paper incorporates amendments and remarks presented during the interview.

#### Amendments:

The amendments to the claims are supported by the claims as previously presented and throughout the specification, and do not introduce new matter into the disclosure. The amendments are made without prejudice in order focus coverage on embodiments of the invention that are of current commercial interest. Applicants reserve the right to introduce claims to extend coverage in this or any related application.

Claims 1-12 and 35-40 relate to hybridization methods using a probe under conditions that it hybridizes specifically to the nucleic acid to be identified or detected. Claims 13-19, 21, and 41-46 relate to amplification methods using one or more primers under conditions that cause amplification of the nucleic acid to be identified or detected. In order to amplify a template using the primer referred to in claim 13, the skilled reader will know that the amplification conditions include a second primer (either specific or non-specific) that works in concert with the first primer so as to cause amplification in a specific fashion, if the target nucleic acid is present.

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Claims 39-40 and 45-46 have been amended to indicate that the sample used in the assay methods has been obtained from a patient having a tumor. The user may wish to conduct the claimed method on such a sample for any worthwhile purposes, including but not limited to what is disclosed in the specification.

The amendments to claims 1-2, 13-14, and 38 do not introduce substantial new limitations. Accordingly, the claims include coverage for all equivalents for which applicants were previously entitled.

Request for Rejoinder:

Applicants hereby renew their request to rejoin claims 23-26 back into the group under examination. The other withdrawn claims (27-34) have now been cancelled.

Claims 23-26 depend from and incorporate limitations of claims in the elected group. Specifically, claim 23 covers amplification primers *for use in the detection method of claim 14*. The primers recited in these dependent claims have the same features as the primers referred to in the last clause of claim 14. The primers consist essentially of 15 or more consecutive nucleotides of SEQ. ID NO:14, which is free of the prior art of record in the same manner as claim 14. Utility of claims 23-26 is demonstrated by the method claims from which they depend.

Accordingly, claims 23-26 can be examined together with the elected group without raising substantive new issues under 35 USC §§ 101, 102, 103, or 112. To save applicants the financial burden and delay of having to file divisional applications for all the groups, applicants respectfully request that claims 23-26 be rejoined into the group under examination.

Patentability:

Examiner Walicka asked during the interview about the relationship between the present disclosure, and the paper published by Lingner et al. having the following citation:

Lingner J, Hughes TR, Shevchenko A, Mann M, Lundblad V, and Cech TR. "Reverse transcriptase motifs in the catalytic subunit of telomerase." *Science*. 1997 Apr 25; 276(5312):561-7.

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The Lingner paper reports cloning and sequence analysis of telomerase genes from *Euplotes aediculatus* and *Saccharomyces cerevisiae*, and identifies reverse transcriptase motifs implicated for catalysis of telomere elongation in vivo.

The present application claims priority to U.S. patent application Ser. No. 08/844,419, filed Apr. 18, 1997, now abandoned — see page 2 of the Amendment filed May 27, 2004. The '419 application provides the sequence of telomerase genes from *Euplotes aediculatus* and *Saccharomyces cerevisiae*, and also provides the motif analysis of the telomerase family. The Medline reference for the Lingner article gives a publication date of April 25, 1997, which is one week after the filing date of the '419 application.

Accordingly, any information in the Lingner article that is relevant to the invention claimed here is predated by the '419 priority application. The Lingner article does not qualify as prior art.

Furthermore, use of telomerase motifs to identify and characterize the human TRT sequence was not invented by the authors of the Lingner article, but by the inventive entity of the present application. Related application USSN 09/766,253 claims the use of telomerase and reverse transcriptase motifs for this purpose. The '253 application is a continuation of USSN 08/846,017, which was CPA of 08/846,017, filed April 25, 1997. The '253 application has been *allowed*, and the issue fee has been paid. The named inventors are Cech, Lingner, Nakamura, Chapman, Morin, Harley, and Andrews. A copy of the allowed claims accompanies this response.

There is no published sequence information available before the priority applications in this series that annotates any substantial part of SEQ. ID NO:224 as an hTRT sequence. Consequently, there is no prior art that motivates or enables the skilled reader to implement the assay methods of claims 1-19, 21, and 35-46, or to make and use the amplification primer pairs of claims 23-26.

Accordingly, the claimed invention is patentable over all the prior art of record in this application, including the Lingner articles and publicly available sequence disclosures.

#### Request for Interview

Applicants respectfully request that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

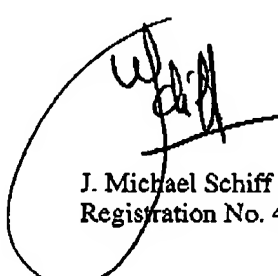
In the event the Examiner determines that there are other matters to be addressed, applicants hereby request an interview by telephone.

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Fees

It is respectfully submitted that no fees are required for entry and consideration of this paper. However, should the Patent Office determine that an extension of time or any other relief is required for further consideration of the application, applicants hereby petition for such relief, and authorize the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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**METHOD FOR IDENTIFYING NUCLEOTIDE SEQUENCES  
ENCODING TELOMERASE PROTEIN**

USSN 09/766,253

*Docket 018/180c  
TTC 015389-002921US  
Apr 25/97 Specification*

**Allowed Claims**

1 to 7. (Cancelled)

8. A method for detecting the presence of polynucleotide sequences encoding at least a portion of telomerase in a biological sample, comprising the steps of:
- obtaining an amino acid sequence encoded in a polynucleotide contained in the biological sample;
  - comparing the amino acid sequence with the telomerase amino acid motif  
W-X<sup>12</sup>-FFY-X<sup>1</sup>-TE,  
wherein X<sup>n</sup> is a sequence of "n" unspecified amino acids; and then
  - determining that the sample contains a polynucleotide encoding at least a portion of telomerase if the sequence obtained in step a) contains said telomerase amino acid motif.

9 to 20. CANCELLED

- The method of claim 8, wherein the telomerase is a telomerase of a single-celled eukaryote.
- The method of claim 8, wherein the telomerase is a mammalian telomerase.
- The method of claim 8, wherein the telomerase is a human telomerase.
- The method of claim 8, wherein the polynucleotide contains SEQ. ID NO:100.
- The method of claim 8, further comprising comparing the sequence determined in step b) with the reverse transcriptase motif R-X<sup>2</sup>-PK-X<sup>4</sup>-R-X<sup>1</sup>-I.
- The method of claim 8, further comprising comparing the sequence determined in step b) with the reverse transcriptase motif F-X<sup>3</sup>-D-X<sup>3</sup>-CYD.
- The method of claim 8, comprising deciding that the sample contains a polynucleotide sequence encoding at least a portion of telomerase if the sequence determined in step b) contains the amino acid motif  
h<sub>1</sub>-X<sup>1</sup>-W-h<sub>2</sub>-X<sup>4</sup>-h<sub>3</sub>-X<sup>2</sup>-h<sub>4</sub>-h<sub>5</sub>-h<sub>6</sub>-h<sub>7</sub>-FFY-X<sup>1</sup>-TE,  
wherein
  - h<sub>1</sub> is L or I;
  - h<sub>2</sub> is L or I;
  - h<sub>3</sub> is V or I;
  - h<sub>4</sub> is L or I;
  - h<sub>5</sub> is L or I;
  - h<sub>6</sub> is R or Q; and
  - h<sub>7</sub> is S, T or C.

**CONFIDENTIAL**